**510(k) Summary**

Company Name: SeaSpine, Inc.
2302 La Mirada Drive
Vista, CA 92081

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Senior Project Engineer
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APR 10 2009

Date Prepared: August 11, 2008

Trade Name: Cambria™

Common Name: Interbody Fusion Device
Classification Name: Intervertebral Fusion Device with Bone Graft, Cervical
21 CFR 888.3080, Product Code ODP, Class II
Orthopedic Review Committee

Device Description: Cambria is an intervertebral fusion device intended to act as a disc spacer and hold bone graft to promote fusion in the cervical spine. Implants are made from PEEK (polyetheretherketone) with radiographic markers and are generally box-shaped with a central canal for receiving bone graft. Cambria is offered in a variety of shapes and sizes to accommodate variations in patient anatomy.

Intended Use: Cambria is intended to be used as an adjunct to spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as neck pain with discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Patients should have received at least six weeks of non-operative treatment prior to treatment with the device. Devices are intended to be implanted via an open, anterior approach and used with autogenous bone and supplemental fixation, such as an anterior plating system.

Substantial Equivalence: Cambria was shown to be substantially equivalent to predicate device(s) through comparison in areas including intended use, design, materials, and function.

Performance Data: Mechanical testing results indicated that Cambria possessed appropriate properties for its intended use and is substantially equivalent to predicate device(s). Clinical data was not required for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 0 2009

SeaSpine, Inc.
% Mr. Jeff Brittan
Senior Project Engineer
2302 La Mirada Drive
Vista, California 92081

Re: K082309
Trade/Device Name: Cambria™
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: March 17, 2009
Received: March 18, 2009

Dear Mr. Brittan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Indications for Use**

**510(k) Number (if known):** K082309

**Device Name:** Cambria™

**Indications for Use:**

Cambria is intended to be used as an adjunct to spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as neck pain with discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Patients should have received at least six weeks of non-operative treatment prior to treatment with the device. Devices are intended to be implanted via an open, anterior approach and used with autogenous bone and supplemental fixation, such as an anterior plating system.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for MKM

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**



**510(k) Number** K082309